

I. Real party in interest

The real party in interest in this application is Medtronic, Inc, assignee of the application.

II. Related appeals and interferences

None

III. Status of the claims

Claims 1 – 2 and 7 - 15 are pending. Claims 3 – 16 and 17 – 58 are cancelled. All pending claims stand rejected. The rejections of claims 1 – 2 and 7 - 15 are hereby appealed.

IV. Status of amendments

The Amendment of December 28, 2010 was entered. Claim 16 was cancelled. The remaining claims were not amended at that time. The Claims Appendix contains clean copies of the claims as finally rejected.

V. Summary of claimed subject matter

The claims on appeal all depend from Claim 1. The subject matter of the claims is therefore summarized by reference to claim 1.

Claim 1

Claim 1 sets forth a medical system.

The system comprises an implantable cardiac pacing pulse generator. The pulse generator (IMD) 1 is illustrated in Figure 6 and described in paragraph 26. As described in paragraph 26 the IMD delivers bipolar pacing stimulation to

the left ventricle using electrodes 656 and 612 as a bipolar stimulation electrode pair.

The system further comprises a first lead, comprising an elongated lead body including a first elongated insulated conductor and a first connector formed at a proximal end thereof; the connector including a first electrical contact electrically coupled at a first polarity to the pacing pulse generator. The first lead 600 is illustrated in Figure 6 and described in paragraph 27, and includes an electrical connector 622 coupled to the IMD 1 and an insulated conductor therein coupled to electrode 656.

The system further comprises a second lead, comprising an elongated lead body including a second elongated insulated conductor and a second connector formed at a proximal end thereof; the connector including a second electrical contact electrically coupled at a second polarity to the pacing pulse generator, the pacing pulse generator comprising means for delivering pulses between the first and second electrical contacts. The second lead 670 is illustrated in Figure 6 and described in paragraph 27, and includes an electrical connector 618 coupled to the IMD 1 and an insulated conductor therein coupled to electrode 612. As noted above, the electrodes 656 and 612 form a bipolar pacing electrode pair between which the pulse generator (IMD) 1 delivers pacing stimulation.

The system further includes a first pacing electrode joined to the first lead body and coupled to the first contact of the first connector via the first conductor, the first electrode adapted for intimate contact with tissue at a first site. The first electrode 656 is described in paragraph 27 and is mounted to first lead 600. Because the electrode is not provided with a porous coating, the metallic surface of the electrode directly contacts tissue at the first site (coronary vein 660).

The system further includes a second pacing electrode joined to the second lead body and coupled to the second contact of the second connector via the second conductor, the second electrode adapted for location at a second

site. The second electrode 612 is described in paragraph 27 and is mounted to second lead 670.

The system further includes a porous layer formed over the second electrode, allowing conduction therethrough while preventing contact between the second electrode and tissue in proximity to the second site. Various embodiments of the porous coating are described in paragraphs The porous layer is described in detail in paragraphs 19 – 22 and is illustrated in Figures 2A - C and 3A – C. The second electrode is adapted for location at a second site (right ventricle 65, Figure 6).

VI. Grounds of rejection to be reviewed on appeal

A. Rejection of claims 1, 2 and 7 – 10 over Carson (US 5,931,862) in view of Helland (US 5,446,254)

This rejection is respectfully traversed.

B. Rejection of claims 11 - 14 over Carson (US 5,931,862)in view of Helland (US 5,446,254) in view of Soukup, et al. (US 5,466,252)

This rejection is respectfully traversed.

C. Rejection of claims 12 - 15 over Carson (US 5,931,862)in view of Helland (US 5,446,254) in view of Hull, et al. (US 5,296,810)

This rejection is respectfully traversed.

VII. Argument

A. Rejection of claims 1, 2 and 7 – 10 over Carson (US 5,931,862) in view of Helland (US 5,446,254)

This rejection is respectfully traversed.

As best understood by Applicants, based upon all of the various statements and positions taken in the Office Actions, the Examiner's final position is as follows, restated in syllogism form:

a) Carson discloses electrodes in which a porous layer formed the electrodes, allowing conduction therethrough while preventing contact between the electrodes and tissue; and

b) Helland discloses delivery of pacing pulses between electrodes on two different leads; and therefore

c) it is obvious to deliver a pacing pulse between an electrode as disclosed in Helland on one lead and an electrode as disclosed in Carson on another lead and to connect a pacing pulse generator to do so.

Applicants do not and have not disputed the facts in the premises a) and b) above. They merely dispute that the conclusion c) follows therefrom.

The Examiner's arguments ignore the fact that neither the Helland nor the Carson reference discloses delivery of pacing pulses between two different types of electrodes. Both expressly disclose delivery of pacing pulses between two electrodes of the same type.

In Carson, the two electrodes relied upon by the examiner (the atrial electrodes) are both coated with a porous coating. In Helland, both electrodes lack the porous coating. Neither discloses nor suggests any benefit that might be obtained by delivering pacing stimulation between two electrodes of the two different types as set forth in the present claims. Both teach precisely the opposite. The Examiner's rejection simply does not address or dispute these facts. As such, it is respectfully asserted that the Examiner's rejection is inadequate under the holding in *Perfect Web Technologies v. InfoUSA*. The Examiner should be familiar with this case because it is expressly incorporated into the USPTO Guidelines for Section 103 rejections.

In particular, the Guidelines require that proposed modifications to cited references obviousness rejections must conform to common sense and that the

rejections must be set forth with sufficient specificity to demonstrate that they do so. In the present case, the Examiner has not addressed the fact that both cited references teach exactly the opposite of the claimed invention. They teach delivery of bipolar pacing stimulation between electrodes of the same type, whether on the same or different leads. Neither suggests any benefit to doing otherwise.

As both references omit the same essential teaching, their combination cannot somehow provide it.

It is respectfully asserted that under the circumstances, the rejection is improper and should be withdrawn.

B. Rejection of claims 11 - 14 over Carson (US 5,931,862) in view of Helland (US 5,446,254) in view of Soukup, et al. (US 5,466,252)

This rejection is respectfully traversed.

This rejection depends upon the erroneous rejection of claim 1 as discussed above. Withdrawal of these rejections is correspondingly requested.

C. Rejection of claims 12 - 15 over Carson (US 5,931,862) in view of Helland (US 5,446,254) in view of Hull, et al. (US 5,296,810)

This rejection is respectfully traversed.

This rejection depends upon the erroneous rejection of claim 1 as discussed above. Withdrawal of these rejections is correspondingly requested.

All remaining claims are therefore believed to be allowable over the Cited references. Withdrawal of the rejections of the remaining claims is respectfully requested.

Finally, if there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned attorney to attend to these matters.

The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

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Date

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VIII. Appendix - Claims on Appeal

1. A medical system, comprising:
  - an implantable cardiac pacing pulse generator;
  - a first lead, comprising an elongated lead body including a first elongated insulated conductor and a first connector formed at a proximal end thereof; the connector including a first electrical contact electrically coupled at a first polarity to the pacing pulse generator;
  - a second lead, comprising an elongated lead body including a second elongated insulated conductor and a second connector formed at a proximal end thereof; the connector including a second electrical contact electrically coupled at a second polarity to the pacing pulse generator, the pacing pulse generator comprising means for delivering pulses between the first and second electrical contacts;
    - a first pacing electrode joined to the first lead body and coupled to the first contact of the first connector via the first conductor, the first electrode adapted for intimate contact with tissue at a first site;
    - a second pacing electrode joined to the second lead body and coupled to the second contact of the second connector via the second conductor, the second electrode adapted for location at a second site; and
    - a porous layer formed over the second electrode, allowing conduction therethrough while preventing contact between the second electrode and tissue in proximity to the second site.

2. The medical system of claim 1, wherein the second electrode includes an outer surface, the porous layer includes an outer surface, and the second lead body includes an outer surface; the outer surface of the second electrode recessed from the outer surface of the second lead body and the outer surface of the porous layer isodiametric with the outer surface of the second lead body.

3 - 6. (Cancelled)

7. The medical system of claim 1, further comprising means to promote wetting of the porous layer.

8. The medical system of claim 7, wherein the means to promote wetting comprises a wetting agent applied to the porous layer.

9. The medical system of claim 8, wherein the wetting agent comprises a surfactant.

10. The medical system of claim 7, wherein the means to promote wetting comprises a surface treatment of the porous layer.

11. The medical system of claim 1, wherein the porous layer has a thickness between approximately 0.005 inch and approximately 0.020 inch.

12. The medical system of claim 1, wherein the porous layer includes pores having sizes ranging, on average, between approximately 0.4 micron and approximately 50 microns.

13. The medical system of claim 12, wherein the pores have sizes ranging, on average, between approximately 0.4 micron and approximately 10 microns.



14. The medical system of claim 12, wherein the pores have sizes ranging, on average, between approximately 10 microns and approximately 20 microns.

15. The medical system of claim 12, wherein the pores have sizes ranging, on average, between approximately 20 microns and approximately 50 microns.

16 - 58. (Cancelled)

IX Appendix – Evidence

None

X. Appendix – Other proceedings

None